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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/659,747	09/11/2003	Alexander Levitzki	26682	3467

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EXAMINER	
JONES, DAMERON LEVEST	
ART UNIT	**PAPER NUMBER**
1618	

DATE MAILED: 07/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/659,747	LEVITZKI ET AL.	
	Examiner	Art Unit	
	D. L. Jones	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-93 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1,2,12,13,27-34,40-42,49-57,60-65,67,68,71-77,81 and 84 is/are rejected.

7)☒ Claim(s) 3-11,14-26,35-39,43-48,58,59,66,69,70,78-80,82,83 and 85-93 is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

APPLICANT'S INVENTION

1. Applicant's invention is directed to radiolabeled compounds, methods of making the compounds, and uses thereof as set forth in independent claims 1, 54, 61, 71, and 84.

Note: Claims 1-93 are pending.

STATUTORY DOUBLE PATENTING

2. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

3. Claims 1, 2, 12, 13, 27-34, 40-42, 49-57, 60-65, 67, 68, 71-77, and 81 are rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-4 and 7-40 of prior U.S. Patent No. 6,562,319. This is a double patenting rejection.

OBVIOUSNESS-TYPE DOUBLE PATENTING

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 1, 42, and 43 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 17 of U.S. Patent No. 6,562,319. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed to radiolabeled compounds of Formula I wherein the radioactive isotope may be iodine

124. The claims differ in that the patented claims disclose that the compound is radiolabeled with iodine 123 or iodine 124 (see claim 17) and the instant invention disclose that the compound is radiolabeled with iodine 124 (see claim 43). It would be obvious to one of ordinary skill in the art at the time the invention was made to radiolabel the compound with iodine 124 because the patented invention discloses the use of either iodine 123 or iodine 124 as possible radioisotopes for labeling the compound. Thus, a skilled practitioner would be motivated to select iodine 124 from the small Markush grouping.

112 SECOND PARAGRAPH REJECTIONS

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1, 50, 54, 61, 68, 71, 81, and 84 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1, line 21: The claims as written are ambiguous because of the phrase 'non-radioactive derivatizing group'. In particular, it is unclear what species Applicant is intending to be compatible with the instant invention. Did Applicant intend to incorporate the species of claim 2? If so, please correct in order that one may readily ascertain what is being claimed. It is noted that Applicant has identified the *radioactive*

derivatizing groups. This rejection is also applicable to claim 54, line 15; claim 61, line 15; claim 71, line 15; and claim 84, line 15.

Claim 50: The claim as written is ambiguous because it is unclear which nuclear imaging technique or techniques Applicant is/are claiming to be compatible with the instant invention.

Claim 54, line 28: The claim as written is ambiguous because of the term 'carboxylic derivative'. In particular, it is unclear what carboxylic derivative Applicant is claiming that is compatible with the instant invention. In addition , in the derivative, it is unclear which portion of the parent compound remains in the derivative. This rejection is also applicable to claim 61, lines 33-34; claim 68, lines 2-3; and claim 81, lines 2-3.

Claim 71, lines 40-41: The claim as written is ambiguous because of the phrase 'reactive α,β unsaturated derivative'. In particular, it is unclear what species Applicant is intending to be compatible with the instant invention.

CLAIM OBJECTIONS

8. Claims 3-11, 14-26, 35-39, 43-48, 58, 59, 66, 69, 70, 78-80, 82, 83, and 85-93 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

SPECIFICATION

9. The disclosure is objected to because of the following informalities: it is unclear whether the instant application is a divisional, continuation, or CIP of 09/802,928. In

particular, it is noted that continuity claimed under 35 USC 120 does not set forth the relationship of the instant application with that of 09/802,928.

Appropriate correction is required.

COMMENTS/NOTES

10. It should be noted that Mishani et al (US Patent No. 6,126,917) cited on the PTO-892 and not used in a rejection contains structurally similar compounds to those of the instant invention. In particular, whiled the patent contains structurally similar compounds, the compounds differ from those of the instant invention in their description of the variables R1 and R2. In the instant invention, the group X-Y(=O)Z is present. However, the definitions of R1 and R2 of the patent do not allow for the presence of X-Y(=O)Z.

11. It should be noted that no prior art has been cited against claims 1-93 of the instant invention. However, Applicant MUST address and overcome the double patenting and 112 rejections above. In particular, the claims are distinguished over the prior art of record because the prior art neither anticipates nor renders obvious a radiolabeled compound, method of making a radiolabeled compound, and use of the radiolabeled compounds as set forth in independent claims 1, 54, 61, 71, and 84. The closest art is Applicant's own work that is cited in the double patenting rejections above.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (571) 272-0617. The examiner can normally be reached on Mon.-Fri., 6:45 a.m. - 3:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

D. L. Jones
Primary Examiner
Art Unit 1618

July 19, 2005